

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	:	Examiner: S. J. Oh
FRANK BUNICK ET AL.	)	
	:	Group Art Unit: 1618
Application No.: 09/896,052	)	
	:	Confirmation No.: 9476
Filed: June 29, 2001	)	
	:	
For: BRITTLE COATING, SOFT CORE	)	
DOSAGE FORM	:	June 9, 2008

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

<b>CERTIFICATE OF ELECTRONIC FILING</b>	
I hereby certify that this correspondence is being transmitted via The Office Electronic Filing System in accordance with 37 CFR 1.6(a)(4).	
June 9, 2008	Ruth Ann Kreiger
<b>Date of Transmission and Signature</b>	<b>Name of Applicant, Assignee, or Registered Representative</b>
/Ruth Ann Kreiger/	
<b>Signature</b>	

AMENDMENT AND PETITION FOR EXTENSION OF TIME

Sir:

Applicants petition to extend the time for responding to the Office Action dated February 7, 2008, for one month from May 7, 2008 to June 9, 2008 (June 7, 2008 falling on a Saturday). Please charge the required petition fee of \$120 to Deposit Account No. 10-0750.

In response to the February 7, 2008 Office Action, please amend the application as follows:

Amendments to the Claims are reflected in the listing of claims, which begins on page 3 of this paper. The Remarks begin on page 7 of this paper.

#### AMENDMENTS TO THE CLAIMS:

The following is a complete listing of the claims and reflects all changes currently being made to the claims. This listing supersedes all earlier versions and all earlier listings of the claims.

Claim 1 (currently amended):       A texture masking oral dosage form comprising

(a)     a unitary soft core comprising a plurality of active agent particles having an average size of greater than about 50  $\mu\text{m}$ , a hydrocolloid, and water; and

(b)     a brittle shell encasing the soft core in an amount of from about 20% to about 50% of the total weight of the texture masking oral dosage form and a thickness of from about 500  $\mu\text{m}$  to about 3000  $\mu\text{m}$ , wherein the weight ratio of active agent particles to shell being from about 1.0:0.5 to about 1.0:15 in the texture masking oral dosage form.

Claim 2 (previously presented):     An oral dosage form of claim 1, wherein the weight ratio of active agent particles to shell being from about 1.0:2 to about 1.0:12.

Claim 3 (previously presented):     An oral dosage form of claim 2, wherein the weight ratio of particles to shell being from about 1.0:4 to about 1.0:9.

Claim 4 (original):     An oral dosage form of claim 1, wherein the soft core is pectin based.

Claim 5 (previously presented):     An oral dosage form of claim 1, wherein the soft core is gelatin based.

Claim 6 (previously presented):     An oral dosage form of claim 1, wherein the soft core has a hardness of about 1 to about 8  $\text{kp}/\text{cm}^2$ .

Claim 7 (previously presented):     An oral dosage form of claim 1, wherein the active agent is selected from the group consisting of acetaminophen, ibuprofen, pseudoephedrine, dextromethorphan, diphenhydramine, chlorpheniramine, calcium carbonate, magnesium hydroxide, magnesium carbonate, magnesium oxide, aluminum hydroxide, mixtures thereof, and pharmaceutically acceptable salts thereof.

Claim 8 (original): An oral dosage form of claim 7, wherein the active agent is acetaminophen or ibuprofen.

Claim 9 (original): An oral dosage form of claim 8, wherein the active agent is acetaminophen.

Claim 10 (previously presented): An oral dosage form of claim 8, wherein the active agent is ibuprofen.

Claim 11 (previously presented): An oral dosage form of claim 3, wherein the active agent is selected from the group consisting of acetaminophen, ibuprofen, pseudoephedrine, dextromethorphan, diphenhydramine, chlorpheniramine, calcium carbonate, magnesium hydroxide, magnesium carbonate, magnesium oxide, aluminum hydroxide, mixtures thereof, and pharmaceutically acceptable salts thereof.

Claim 12 (original): An oral dosage form of claim 11, wherein the active agent is acetaminophen or ibuprofen.

Claim 13 (original): An oral dosage form of claim 12, wherein the active agent is acetaminophen.

Claim 14 (original): An oral dosage form of claim 12, wherein the active agent is ibuprofen.

Claim 15 (currently amended): A texture masking oral dosage form comprising

- (a) a unitary soft core comprising a plurality of acetaminophen particles having an average size of greater than about 50  $\mu\text{m}$ , a hydrocolloid, and water; and
- (b) a brittle shell enveloping the soft core in an amount of from about 20% to about 50% of the total weight of the texture masking oral dosage form and a thickness of from about 500  $\mu\text{m}$  to about 3000  $\mu\text{m}$ , wherein the weight ratio of active agent to shell being from about 1.0:4 to about 1.0:9 in the texture masking oral dosage form.

Claim 16 (currently amended): A texture masking oral dosage form comprising

- (a) a unitary soft core comprising a plurality of ibuprofen particles having an average size of greater than about 50  $\mu\text{m}$ , a hydrocolloid, and water; and

(b) a brittle shell enveloping the soft core in an amount of from about 20% to about 50% of the total weight of the texture masking oral dosage form and a thickness of from about 500  $\mu\text{m}$  to about 3000  $\mu\text{m}$ , wherein the weight ratio of particles to shell being from about 1.0:4 to about 1.0:9 in the texture masking oral dosage form.

Claim 17 (currently amended): A texture masking oral dosage form comprising

(a) a unitary soft core comprising a plurality of active agent particles having an average size of greater than about 50  $\mu\text{m}$ , a hydrocolloid, and water; and

(b) a brittle shell encasing the soft core in an amount of from about 20% to about 50% of the total weight of the texture masking oral dosage form and a thickness of from about 500  $\mu\text{m}$  to about 3000  $\mu\text{m}$ , wherein the weight ratio of active agent particles to shell being from about 1.0:0.5 to about 1.0:15 and wherein the soft core has a hardness of about 1 to about 8  $\text{kp/cm}^2$ [[15]] in the texture masking oral dosage form.

Claim 18 (previously presented): An oral dosage form of claim 1, wherein the weight ratio of active agent particles to shell being from about 1.0:2 to about 1.0:12.

Claim 19 (previously presented): An oral dosage form of claim 18, wherein the weight ratio of active agent particles to shell being from about 1.0:4 to about 1.0:9.

Claim 20 (previously presented): An oral dosage form of claim 17, wherein the soft core is pectin based.

Claim 21 (previously presented): An oral dosage form of claim 1, wherein the soft core is gelatin based.

Claim 22 (previously presented): An oral dosage form of claim 17, wherein the active agent is selected from the group consisting of acetaminophen, ibuprofen, pseudoephedrine, dextromethorphan, diphenhydramine, chlorpheniramine, calcium carbonate, magnesium hydroxide, magnesium carbonate, magnesium oxide, aluminum hydroxide, mixtures thereof, and pharmaceutically acceptable salts thereof.

Claim 23 (previously presented): An oral dosage form of claim 22, wherein the active agent is acetaminophen or ibuprofen.

Claim 24 (previously presented): An oral dosage form of claim 23, wherein the active agent is acetaminophen.

Claim 25 (previously presented): An oral dosage form of claim 23, wherein the active agent is ibuprofen.

### REMARKS

Claims 1-25 are pending. Claims 1 and 15-17 have been amended to further define Applicants' invention. Claims 1 and 15-17 are in independent form. Favorable reconsideration and allowance of the subject application are respectfully requested in view of the following comments.

Claims 1-25 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 6,060,078 (*Lee*) in view of U.S. Patent No. 4,800,087 (*Mehta*), U.S. Patent No. 4,753,790 (*Silva*), and U.S. Patent No. 4,260,596 (*Mackles*). Applicants respectfully traverse these rejections, in view of the comments set forth below.

One of the notable features of amended Claim 1 is the unitary soft core, which is comprised of a plurality of active agent particles having an average size of greater than about 50µm, a hydrocolloid, and water.

*Lee*, *Mehta*, *Silva*, and *Mackles* were discussed previously in Applicants' responses dated April 23, 2007 and January 28, 2008.

Applicants respectfully submit that *Lee*, *Mehta*, *Silva*, and *Mackles*, do not disclose or suggest a unitary soft core comprised of a plurality of active agent particles having an average size of greater than about 50µm, a hydrocolloid, and water.

Applicants note that in column 8, lines 29-43, *Mehta* discloses a method of forming a pharmaceutical core. A powdered or granular active agent, and diluent or bulking agent are used to form a wet mass utilizing water or a pharmaceutically acceptable solvent. Notably, the mixture is subsequently dried, creating a dry pharmaceutical core (*see*, for example, column 8, lines 37-40). Thus, the pharmaceutical core of *Mehta* is not soft.

As such, Claim 1 is patentable over *Lee, Mehta, Silva* and/or *Mackles*, whether considered separately or in any permissible combination.

Claims 15, 16 and 17 are directed to compositions that are similar to the composition of Claim 1 in many respects. Claims 15, 16 and 17 all include a unitary soft core comprised of a plurality of active agent particles having an average size of greater than about 50µm, a hydrocolloid, and water. In Claim 15 the active agent is acetaminophen and in Claim 16 the active agent is ibuprofen. Accordingly, for at least the same reasons discussed above for Claim 1, Claims 15, 16 and 17 are patentable over *Lee, Mehta, Silva* and/or *Mackles*, whether considered separately or in any permissible combination.

The remaining claims directly or indirectly depend from Claims 1, 15, 16 or 17. Therefore, each of the remaining claims is also patentable over *Lee, Mehta, Silva* and/or *Mackles*, whether considered separately or in any permissible combination.

In view of the foregoing remarks, Applicants respectfully request favorable reconsideration and allowance of the claims in the present application.

Applicants' undersigned attorney may be reached in our office at the telephone number provided below.

Respectfully submitted,

/Victor Tsu/

---

Attorney for Applicants

Victor Tsu

Registration No. 46,185

Johnson & Johnson  
One Johnson & Johnson Plaza  
New Brunswick, NJ 08933-7003  
(732) 524-1767